No. 14802

United States
Court of Appeals
for the Ninth Circuit

A. SCHLESSING, claimant of 75 articles of device, more or less, designated as "The Schlessing Ultrasoniseur", together with their labeling, Appellant,

vs.

UNITED STATES OF AMERICA, Appellee.

Transcript of Record

Appeal from the United States District Court for the Southern District of California, Central Division

Phillips & Van Orden Co., 870 Brannan Street, San Francisco, Calif. —8-31-55

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[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in italic; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in italic the two words between which the omission seems to occur.]

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* Page numbers appearing at foot of page of original Transcript of Record.

In the United States District Court for the Southern District of California, Central Division

Civil No. 14482-WB

UNITED STATES OF AMERICA, Libelant,

vs.

75 Articles of Device, more or less, designated as "The Schlessing Ultrasoniseur", together with their labeling, Respondents.

LIBEL OF INFORMATION

To the Honorable Judges of the United States District Court for the Southern District of California:

Now comes the United States of America, by Walter S. Binns, United States Attorney for the Southern District of California, and shows to the Court:

1. That this Libel is filed by the United States of America, and prays seizure and condemnation of certain articles of device together with their labeling as hereinafter set forth, in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.).

2. That A. Schlessing and Company, Inc., shipped in interstate commerce from St. Louis, Missouri, to Perfect Health Institute, at Los Angeles and Santa Monica, California, and to other consignees located within the jurisdiction of this Court, via Railway Express Agency and other means, during the period from July 1, 1951, to September 4, 1952, 75 articles of device, more or less, designated "The Schlessing Ultrasoniseur". [2]

3. That the aforesaid articles of device, when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, were accompanied by certain labeling, including the following items of written, printed, and graphic matter, which contain statements relating to said articles of device and which constitute an essential part of the distributional scheme to promote the sale of said articles:

(a) Pamphets entitled "Therapeutics by Ultrasonics".

(b) Leaflets entitled "Please Read Carefully. The Schlessing Ultrasoniseur * * *"

(c) Leaflets entitled "that they may WALK again * * *"

(d) Sheets entitled "Reports on Ultrasonic Physical Medicine from American Users".

(e) Form letters from A. Schlessing and Company headed, "Dear Doctor: * * *"

(f) Guarantees and order blanks regarding Schlessing Ultrasoniseur.

4. That the aforesaid articles of device, when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, were misbranded within the meaning of 21 U.S.C. 352(a) in that said labeling when taken as a whole as well as through specific claims, and in the setting in which it is presented, contains statements which represent and suggest that the said devices provide an adequate and effective treatment for the cure of "abscesses, arthritis, arthrosis deformans, asthma bronchiale, morbus bech-

terew, bronchiektasy, claudicato intermittens, furunclosis, sciatica, carbunculosis, lumbago, mastitis, mylagia, panaritia, paronyschosis, periarthritis, humeroscapularis, phlegmones, prostata hyperthrophy, sinusitis maxillaris, ulcus cruris, effusions of the joints, abscesses of perspiratory glands, gingivitis, stomatitis, paradentosis, pulpitis, infiltrations, especially granulomes, bursitis, Dupuytren's contracture, endangitis obliterans, fistulae, lymphangitis, paronychia, polyarthritis rheumatica, postoperative pains, morbus raynaud, tendovaginitides, trigeminal neuralgiae, thrombophlebitides, ulcus ventriculi," kidney stones, spinal arthritis, gum boils, kidney colic, gastric ulcer, and asthma, which statements are false and misleading. [3]

5. That the aforesaid articles of device, when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, were further misbranded within the meaning of 21 U.S.C. 352(a) in that the following statements contained in their labeling are false and misleading:

Leaflets entitled "Please Read Carefully"

"This Machine Is Absolutely Safe"

Leaflets entitled "that they may WALK again * * *"

"Is the Schlessing Ultrasoniseur Difficult to Operate?

"Not at all. The technique if (sic) the very simplest. No special skill, no involved instructions and no long experience is necessary to use the Schlessing Ultrasoniseur properly."

"Is the Schlessing Ultrasoniseur Safe?

"Yes. With ordinary precautions. Ultrasoniseur treatments are absolutely painless. There are no contra-indications. No danger of deep burns, tissue damage or irritation. Equally important, there are no possible harmful effects to the person administering treatment."

6. That the aforesaid articles of device, when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, were also misbranded within the meaning of 21 U.S.C. 352(f)(1) in that their labeling fails to bear adequate directions for use for the purposes for which they are intended.

7. That the aforesaid articles of device, when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce, were adulterated within the meaning of 21 U.S.C. 351(c) in that their strength differs from and their quality falls below that which they purport and are represented to possess, since their ability to produce total sound output (ultrasonic) differs materially from the ability which they are represented to possess and the output meter (dosimeter) does not accurately gauge the energy density output of said articles. [4]

8. That the aforesaid articles and labeling are in the possession of Perfect Health Institute, 636 South Broadway, Los Angeles, and 309 Santa Monica Boulevard, Santa Monica, and elsewhere within the jurisdiction of this Court.

That by reason of the foregoing, the aforesaid

articles including their labeling are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to the provisions of said Act, 21 U.S.C. 334.

Wherefore, Libelant prays that process in due form of law according to the course of this Court in cases of admiralty jurisdiction issue against the aforesaid articles of device including their labeling; that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this Court decree the condemnation of the aforesaid articles of device including their labeling and grant Libelant the costs of this proceeding against the claimant of the aforesaid articles; that the aforesaid articles of device including their labeling be disposed of as this Court may direct, pursuant to the provisions of said Act; and that Libelant have such other and further relief as the case may require.

Dated: September 5, 1952.

WALTER S. BINNS,
United States Attorney
CLYDE C. DOWNING,
Asst. U. S. Attorney, Chief, Civil Division
/s/ TOBIAS G. KLINGER,
MAX F. DEUTZ,
Asst. U. S. Attorneys,
Attorneys for Libelant [5]

[Endorsed]: Filed September 5, 1952.

[Title of District Court and Cause.]

CLAIM OF A. SCHLESSING

Now appears before this Honorable Court, A. Schlessing, 3521 Lindell Boulevard, St. Louis 3, Missouri, intervening in this proceeding as the duly authorized agent of the owners and consignees of the devices under seizure, and also as the president of A. Schlessing and Company, Inc., which manufactured said devices, and makes claim to said articles as the same are attached by the United States Marshal for this District under process of this Court at the instance of the United States of America, libelant;

And said claimant avers he has been duly authorized by all the owners and consignees of the said devices to act as their duly authorized agent in this proceeding;

Wherefore he prays to defend accordingly.

/s/ A. SCHLESSING [6]

Duly Verified. [7]

[Endorsed]: Filed October 22, 1952.

[Title of District Court and Cause.]

CONSENT DECREE OF CONDEMNATION

On September 5, 1952, a Libel of Information against the above described articles was filed in this Court on behalf of the United States of America by the United States Attorney for this District. The

Libel alleges that the articles proceeded against are devices which were shipped in interstate commerce and which are adulterated and misbranded in violation of the Federal Food, Drug, and Cosmetic Act. Pursuant to Monition issued by this Court, the United States Marshal for this District seized 47 of said articles together with their labeling consisting of various items of literature. Thereafter, A. Schlessing of St. Louis, Missouri, intervened as a claimant in this proceeding. Claimant consents that a Decree, as prayed for in the Libel, be entered condemning the articles under seizure.

The Court being fully advised in the premises, it is on motion of the parties hereto—

Ordered, Adjudged, and Decreed that the articles of device under [8] seizure are adulterated and misbranded as alleged in the Libel in violation of 21 U.S.C. 351(c), 352(a), and 352(f)(1), and are therefore hereby condemned pursuant to 21 U.S.C. 334 (a); and it is further

Ordered, Adjudged, and Decreed, pursuant to 21 U.S.C. 334(e), that the United States of America shall recover from said Claimant court costs and fees, (and storage and other proper expenses, as taxed herein) to wit, the sum of $35.00; and it is further

Ordered, Adjudged, and Decreed that the United States Marshal for this district shall deliver all of the aforesaid literature to a representative of the U. S. Food and Drug Administration for investigational and exhibit purposes; and

Claimant having petitioned this Court that the

condemned articles of device (without the aforesaid literature) be delivered to him pursuant to 21 U.S.C. 334(d), it is further

Ordered, Adjudged, and Decreed that the United States Marshal for this district shall release said articles (without the aforesaid literature) from his custody to the custody of the Claimant for the purpose of attempting to bring said articles into compliance with law, if the Claimant, within 20 days from the date of the Decree (a) pays in full the aforementioned court costs and fees, and pays to the United States Marshal all storage and other proper expenses of the proceeding herein, and (b) executes and files with the Clerk of this Court a good and sufficient penal bond with surety in the sum of Thirty Thousand Dollars ($30,000.00), approved by this Court, payable to the United States of America, and conditioned upon the Claimant's abiding by and performing all the terms and conditions of this Decree and of such further Orders and Decrees as may be entered in this proceeding; and it is further

Ordered, Adjudged, and Decreed that:

(1) After the filing of the bond in this Court, the Claimant shall at his own expense cause the said articles of device to be shipped to his place of business at 3521 Lindell Boulevard, St. Louis 3, Missouri. When the articles arrive there, Claimant shall give written notice to the St. Louis District, Food and Drug Administration, Federal Security Agency, Room 1007 New Federal [9] Building, 1114 Market Street, St. Louis 1, Missouri, that the articles have

arrived and that the Claimant is prepared to attempt to bring them into compliance with law under the supervision of a duly authorized representative of the Federal Security Administrator.

(2) The Claimant shall at all times, until the articles have been released by a duly authorized representative of the Federal Security Administrator, retain intact the entire lot comprising said articles for examination or inspection by said representative, and shall maintain the records or other proof necessary to establish the identity of said lot to the satisfaction of said representative.

(3) The Claimant shall not commence operations for bringing the articles into compliance with law, or otherwise altering their condition or identity, until he has received authorization to do so from a duly authorized representative of the Federal Security Administrator.

(4) The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of said articles or any part of them until a duly authorized representative of the Federal Security Administrator shall have had free access thereto in order to take any samples or make any tests or examinations that are deemed necessary, and shall in writing have released such articles for shipment, sale, or other disposition. Claimant shall make no distribution of said articles or any part of them except in strict accord with such terms and conditions as may be included in said written release.

(5) Within six months from the date of the filing

of the bond in this Court, Claimant shall complete the process of bringing said articles into compliance with law under the supervision of a duly authorized representative of the Federal Security Administrator.

(6) The Claimant shall abide by the decisions of said duly authorized representative of the Federal Security Administrator, which decisions shall be final. If Claimant breaches any conditions stated in this Decree, or in any subsequent Decree or Order of this Court in this proceeding, Claimant shall return the articles immediately to the United States Marshal for this district [10] at Claimant's expense, or shall otherwise dispose of them pursuant to an Order of this Court.

(7) The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State or Territory (as defined in said Act) in which they are sold or disposed of.

(8) The Claimant shall compensate the United States of America for cost of supervision at the rate of $3.00 per hour per representative for each hour actually employed in the supervision of the aforesaid operations, as salary or wage; where laboratory work is necessary, at the rate of $3.50 per hour per person for such laboratory work; where subsistence expenses are incurred, at the rate of $9.00 per day per person for such subsistence expenses. Claimant shall also compensate the United States of America for necessary traveling expenses

which may be incurred in connection with the supervisory responsibilities of said Federal Security Administrator.

(9) If requested by a duly authorized representative of the Federal Security Administrator, Claimant shall furnish to said representative duplicate copies of invoices of sale of the released articles, or shall furnish such other evidence of disposition as said representative may request.

The United States Attorney for this district, on being advised by a duly authorized representative of the Federal Security Administrator that the conditions of this Decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the bond given in this proceeding shall be canceled and discharged; and it is further

Ordered, Adjudged, and Decreed that if the Claimant does not avail himself of the opportunity to repossess the condemned articles in the manner aforesaid, the United States Marshal for this district shall retain custody of said articles pending the issuance of an order by this Court regarding their disposition; and it is further

Ordered, Adjudged, and Decreed that this Court expressly retains jurisdiction to issue such further Decrees and Orders as may be necessary to the proper disposition of this proceeding, and that should the Claimant fail [11] to abide by and perform all the terms and conditions of this Decree, or of such further Order or Decree as may be entered in this proceeding, or of said bond, then said bond shall on motion of the United States of America in

this proceeding be forfeited and judgment entered thereon.

Dated: October 22, 1952.

/s/ WM. M. BYRNE,
United States District Judge

We hereby expressly consent to the entry of the foregoing Decree.

WALTER S. BINNS, U. S. Attorney
CLYDE C. DOWNING, Asst. U.S. Attorney,
Chief of Civil Division,
/s/ TOBIAS G. KLINGER, Asst. U.S. Attorney
Attorneys for Libelant.
/s/ A. SCHLESSING, Claimant,
/s/ SPENCER E. VAN DYKE,
Attorney for Claimant. [12]

[Marginal Note]: Modified by Stip. & Ord. fld. 10/20/53 & Dktd. & ent. 10/22/53. E. L. Smith, Clerk, by C. A. Simmons, Deputy.

[Endorsed]: Judgment entered and filed October 22, 1952.

[Title of District Court and Cause.]

STIPULATION AND ORDER SCHEDULING FURTHER COURT PROCEEDINGS

It is hereby stipulated by the parties to this proceeding, through their respective counsel, as follows:

(1) In attempting to carry out the terms of the

Consent Decree of Condemnation filed in this cause on October 22, 1952, the parties are not in agreement as to whether certain action proposed by the Claimant would be in compliance with law.

(2) This disagreement hinges upon an interpretation of the Chiropractic Act of the State of California, and should be resolved by this Court.

(3) To facilitate an orderly and thorough presentation of this matter without offering any oral testimony, it is agreed that upon approval by this Court the parties will adhere to the following schedule for the filing of papers with the Clerk of the Court:

(a) May 24, 1954. Claimant will file a motion to compel administrative approval of Claimant's proposed method of distribution of [13] those devices under seizure which have been satisfactorily reworked from a physical standpoint. Together with this motion, there will be filed a stipulation of pertinent facts which are not in dispute, a stipulation as to the precise issues before the Court, and affidavits in support of Claimant's motion if Claimant feels that affidavits are necessary.

(b) June 21, 1954. Libelant may file such affidavits as it deems advisable.

(c) July 19, 1954. Claimant will file his opening brief.

(d) August 16, 1954. Libelant will file its answering brief.

(e) August 30, 1954. Claimant may file a reply brief.

(f) September 27, 1954. Oral argument will be held before the Court at 2 p.m.

(4) The "Stipulation and Order Extending Time for Compliance with Decree", entered by this Court on October 20, 1953, may be modified to suspend the time limits within which the devices under seizure may be brought into compliance with law, pending further order of this Court after the instant issue has been adjudicated.

Dated: April 14, 1954.

LAUGHLIN E. WATERS,
United States Attorney
/s/ MAX F. DEUTZ,
Asst. U. S. Attorney, Chief of Civil Division
Attorneys for Libelant

/s/ SPENCER E. VAN DYKE,
/s/ JACK HILDRETH,
Attorneys for Claimant

It Is So Ordered this 15 day of April, 1954.

/s/ WM. M. BYRNE,
United States District Judge [14]

[Endorsed]: Filed April 15, 1954.

[Title of District Court and Cause.]

STIPULATION AS TO ISSUE

It is hereby stipulated by the parties to this proceeding, through their respective counsel, that the issue presented by Claimant's Motion is as follows:

Is a chiropractor, who is licensed under the California Chiropractic Act, a practitioner licensed by law to use or direct the use of devices such as the six reconditioned ultrasonic therapeutic devices involved in this case, so as to satisfy the requirements of 21 C.F.R. §1.106(e), as amended, and exempt the devices from complying with 21 U.S.C. 352(f)(1)?

Dated: May 21, 1954.

LAUGHLIN E. WATERS,
United States Attorney

/s/ MAX F. DEUTZ,
Asst. U. S. Attorney, Chief of Civil Division
Attorneys for Libelant

/s/ SPENCER E. VAN DYKE,
/s/ JACK HILDRETH,
Attorneys for Claimant [16]

[Endorsed]: Filed May 24, 1954.

[Title of District Court and Cause.]

STIPULATION OF FACTS

It is hereby stipulated by the parties to this proceeding, through their respective counsel, as follows:

(1) Pursuant to the Consent Decree of Condemnation entered herein on October 22, 1952, the 47 ultrasonic devices under seizure were released by the United States Marshal for this District to the custody of the Claimant to be brought into compliance with law under the supervision of the Department of Health, Education, and Welfare.

(2) Claimant arranged to have said 47 devices shipped to his place of business at St. Louis, Missouri, where six of the devices were reconditioned from a physical standpoint to the satisfaction of the Department. Reconditioning of the remaining 41 devices has been suspended until a final decision is reached regarding the legality of Claimant's proposed method of distribution of the six reconditioned devices.

(3) Appended as Exhibit A is a copy of the revised labeling which [17] Claimant has proposed for said six reconditioned devices and to which the Department has no objection, provided that the "Caution" legend required by 21 C.F.R. §1.106(d)(2)(i) appears on the label of each such device.

(4) Ultrasonic therapy based upon the use of said six reconditioned devices involves the application of high frequency sound waves in the treat-

ment of patients by producing rapidly alternating compressions and rarefactions within the tissues. When such therapy is applied to the surface of the body therapeutically, the sound waves penetrate the body and may affect tissues of the body located inches beneath the surface.

(5) Ultrasonic therapy cannot be employed safely and efficaciously by the layman in self-medication, but requires competent supervision in its administration. Adequate directions for unsupervised lay use cannot be written for ultrasonic devices, within the meaning of 21 U.S.C. 352(f)(1). Interstate distribution which would not violate the Federal Food, Drug, and Cosmetic Act must therefore comply with the regulations which exempt devices from bearing adequate directions for use in their labeling. [21 C.F.R. §1.106, as amended]. One provision of these regulations exempts a device which is shipped to "a practitioner licensed by law to * * * use or direct the use of the device." [21 C.F.R. §1.106(e)].

(6) Claimant desires to ship the six reconditioned devices to the owners thereof residing in California who are licensed as chiropractors under the California Chiropractic Act, and in whose possession said devices were seized at the outset of this proceeding. The Department of Health, Education, and Welfare has advised the Claimant that such distribution would not be in compliance with law since, in the judgment of the Department, California chiropractors are not practitioners licensed by law

to use or direct the use of ultrasonic devices, as [18] required by 21 C.F.R. §1.106(e).

Dated: May 21, 1954.

LAUGHLIN E. WATERS,
United States Attorney
/s/ MAX F. DEUTZ,
Asst. U. S. Attorney, Chief of Civil Division,
Attorneys for Libelant
/s/ SPENCER E. VAN DYKE,
/s/ JACK HILDRETH,
Attorneys for Claimant [19]

EXHIBIT A

Directions for Use of the Schlessing Ultrasoniseur in Ultrasonic Therapy

Introduction

The Schlessing Ultrasoniseur is an electrical instrument that transmits inaudible sound waves into the body. This transmission is accomplished by means of a special transducer head containing a quartz crystal. This device is used in applying ultra high frequency sound waves to the body. This vibratory property of certain crystals such as quartz was observed in 1917 by the French Physicist Langevin and is called the "piezo-electric effect".

Although Ultrasonic Therapy has been practiced in Europe for years, the domestic application of ultrasonics in physical medicine is relatively new. The Schlessing Ultrasoniseur combines the latest

advances in mechanical design with the newer knowledge of ultrasonic therapy to bring you an instrument calibrated and regulated to deliver 0.5 watt of energy per square centimeter of transducer head. Animal experimentation[1] has shown that when the Schlessing Ultrasoniseur is used according to directions, a moderate amount of energy is inducted into the tissue and bony structures but no observable damage results therefrom as determined by micropathological examination of various tissues and bones. However, it is of the utmost importance that treatments be given by a doctor thoroughly familiar with the potentialities of the apparatus inasmuch as there is always the possibility of tissue damage from the reflective qualities of ultrasound by causing localized over-heating of bone and muscle when the energy rays are concentrated too long in one place.

Ultrasound has therapeutic value partially because of its selective heating effect. As a result, a promising new instrument is available to the practitioner in the field of physical medicine.

Advantages of the Ultrasoniseur

Ultrasonic Therapy is so new in this country that its possibilities are just beginning to be investigated. An ultrasonic generator has advantages that

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[1] Younger, F. M. The Effect of Multiple Treatments on New Zealand White Rabbits with the Schlessing Ultrasoniseur, unpublished report, Scientific Associates, Inc., St. Louis, Mo., January (1953).

no other instrument presently available to the physician possesses such as:

1. Efficient transfer of energy.[2]

2. Good beaming and good depth of penetration of sound waves.[2]

3. Energy absorbed to a greater extent in muscle than in fat.[2]

4. Fair dosage determination.[2]

5. Selective heating at the tissue-bone interfaces.[2]

(6) The relative safety of a low (0.5 watt per square centimeter) output. [21]

Indications

Ultrasonic generators with outputs of 2.5—3.5 watts of energy per square centimeter have proven useful as a therapeutic adjunct in the treatment of osteorthritis and bursitis.[3] The Ultrasoniscur with its lower energy output of 0.5 watt per square centimeter may also be employed as an experimental procedure in the treatment of osteoarthritis and bursitis, Aldes, et al.,[4] recently report that in a clinical study of 233 patients suffering with chronic

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[2] Schwan, H. P., Carstensen, E. L. Advantages and Limitations of Ultrasonics in Medicine, J.A. M.A., May 10, 1952, Vol. 149, No. 2.

[3] Newman, M. K., and Murphy, A. J. Application of Ultrasonics in Chronic Rheumatic Diseases. The Journal of the Michigan State Medical Society, Sept. 1952, Vol. 51, No. 9.

[4] Aldes, J. H., and Jadeson, W. J. Ultrasound Therapy in Arthritis, Annals Western Medicine and Surgery, 6, 545-550, 1952.

hypertrophic arthritis of the cervical or lumbar spine, 103 or 44% seemed to be permanently improved, 63 or 27% were somewhat benefitted and no patient was harmed; 64 patients apparently failed to be benefitted by the treatment.

Clinical work to date with the low energy output Schlessing Ultrasoniseur has shown encouraging results in the treatment of bursitis. The instrument is recommended for use as a therapeutic adjunct in the treatment of the above named conditions.

Operating Instructions

After attaching the power plug to a 110 volt A.C. wall socket and making sure the transducer coaxial cable is properly connected to the receptacle on the front of the generator, turn the time switch to the desired length of treatment which, should not exceed 6 minutes. The red light on instrument will then go on, indicating it is being charged.

After approximately 10-15 seconds the meter will indicate a reading. Thereupon advance the Output control to a point where the meter needle is in the tune range as marked on the meter. Then adjust the Tuning control for a minimum dip in the meter reading. When the needle is at a minimum do not turn the tuning control any further.

Now that the instrument is in tune, advance the Output control to the desired output. The output meter is calibrated in watts per square centimeter (W/cm^2). The transducer crystal is 8 square centimeters in area. When the output meter reads .5 W/cm^2 the power output of the transducer is then .5 x 8, = total of 4 watts induction.

Caution

Do not attempt to advance the Output control above point where meter reads .5 w/cm². For check purposes, a simple physical test should precede treatment. Out of an eye dropper place 1 or 2 drops of water on the transducer head and if it is emitting sound energy the water will bubble (appear to boil) and disperse.

Method of Treatment

Before turning on the machine, prepare your patient for treatment. The area to be treated should be well defined and thoroughly covered with heavy mineral oil or lanolin prior to treatment. When this is done and not until then, turn on your instrument. [22]

After the water test has been made, apply transducer head flat against the skin and rotate slowly in circles large enough to cover entire surface under treatment at about 10 to 30 circles per minute, according to the size of the affected area. Total length of treatment not to exceed 6 minutes. Any air space between the transducer head and the skin destroys the effectiveness of the instrument by preventing transfer of energy to the patient.

As an added precaution, after several seconds of treatment always ask patient whether any sensation is felt. If more than gentle warmth is reported reduce energy output below 0.5 w/cm² until patient reports no discomfort or tingling sensation. This procedure may be necessary for the first two or

three treatments in cases where severe pain is present before initial treatment.

The number of treatments necessary to alleviate a given condition will depend on the mutual observations of the physician and the patient. Exposure time should be limited to not more than six minutes a treatment for a maximum of twelve treatments given once daily. However, if patient is available, a morning and evening treatment of 3-4 minutes each can be given.

Very important. Never hold transducer head still while in contact with the skin, but keep in constant motion as outlined above. It is imperative that the physician give his undivided attention to use of the instrument during treatment. Although the energy output has been held nearly to a minimum, the sound waves emitted by the Ultrasoniseur are capable of causing damage if the instructions are not carried out as written.

Small localized areas that are difficult to get at, are best treated by placing a rubber sheath or condom, half distended with tepid water and well oiled, over the member and transducer head is then circulated slowly over the rubber sheath.

Ultrasonic waves travel with very little energy loss through water or oil but the impedance rate is very high through air. In Europe under water treatments are used where direct contact is not practical. Transducer head is then rotated around the area of treatment within appr. 1 inch distance. No actual contact should be made. Length of treatment same as in contact. While the under water

treatment is efficient, the condom is preferable because it is faster, less messy and more positive.

Contraindications

Treatment should not be given directly over the cardiac region.

Children should not be treated.

Malignancies.

Treatment should not be given in the vicinity of the brain, particularly over the eyes, ears, forehead and pate.

Treatment should not be given over areas where the skin suffers from any sensory impairment. [23]

Treatment should not be given Directly over the spinal column.

Treatment should not be given over reproductive organs.

Tuberculosis.

Pregnancy.

Energy Output

The Schlessing Ultrasoniseur oscillates at a frequency of approximately 1. megacycle per second. The effective area of the head, which coincides with the crystal area, is 8 square centimeters. The sonic waves given off are continuous and the energy output averages 0.5 Watts per square centimeter. This is an average value since the energy input is 4 Watts. The sonic energy actually given off at the center of the head has a maximum value of approximately two times the average output of 0.5 Watts per square centimeter.

Caution

Do not attempt to calibrate or set your Schlessing Ultrasoniseur in variance with the above instructions. If for any reason it becomes inoperative, notify us immediately.

A. Schlessing & Company, Inc.

Copyrighted 7-24-53 A. S. & Co., Inc. [24]

[Endorsed]: Filed May 24, 1954.

[Title of District Court and Cause.]

MOTION TO COMPEL ADMINISTRATIVE APPROVAL OF CLAIMANT'S PROPOSED METHOD OF DISTRIBUTING DEVICES UNDER SEIZURE

Claimant now moves this Court to order the Department of Health, Education, and Welfare[1] to approve Claimant's proposed method of distribut-

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[1] The Consent Decree of Condemnation filed in this case on October 22, 1952, directed that the condemned devices be brought into compliance with law under the supervision of the Federal Security Administrator who was then the head of the Federal Security Agency. On April 11, 1953, pursuant to Reorganization Plan No. 1 of 1953 and 67 Stat. 18, the Federal Security Agency was abolished and the Department of Health, Education, and Welfare established to administer the functions formerly in the said Agency under the supervision and direction of the Secretary of that Department. (18 Fed. Reg. 2053).

ing those of the devices under seizure which have been reconditioned from a physical standpoint to the satisfaction of the Department, and Claimant asserts the following grounds for this motion:

(1) Six of the ultrasonic devices under seizure have been reconditioned from a physical standpoint to the satisfaction of said [25] Department, pursuant to the Consent Decree of Condemnation entered in this case. Labeling for these devices has been prepared by the Claimant, and the devices are now ready for distribution.

(2) Claimant has proposed to ship these reconditioned devices to chiropractors who reside in California and are licensed under the California Chiropractic Act. In Claimant's opinion, such chiropractors are licensed to use and direct the use of ultrasonic therapeutic devices in their professional practice. Shipment of the devices to these chiropractors would comply with the regulations (21 C.F.R. 1.106(e)) which exempt devices from meeting the requirements of 21 U.S.C. 352(f)(1). Such shipments would therefore be in "compliance with law" as specified in paragraph (1) of the Consent Decree of Condemnation.

(3) Said Department has refused to approve Claimant's proposed method of distribution, basing its refusal upon an erroneous interpretation of the scope of a license granted under the California Chiropractic Act. The Department's conclusion that a chiropractor licensed in California, is not authorized to use or direct the use of ultrasonic therapeutic devices such as those six devices that are in

question here, is a mistaken one, as the said devices are used in physiotherapy which is a part of the practice of Chiropractic under the California Chiropractic Act.

Dated: This 21st day of May, 1954.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By JACK E. HILDRETH,
Attorneys for Claimant [26]

[Endorsed]: Filed May 24, 1954.

[Title of District Court and Cause.]

AFFIDAVIT OF DR. LEE H. NORCROSS, D.C.

State of California,
County of Los Angeles—ss.

Dr. Lee H. Norcross, D.C., being first duly sworn, deposes and says:

That affiant enrolled as a student in the Los Angeles College of Chiropractic in May of 1922 after investigating various schools of chiropractic, course of instruction, teaching methods, and reputation of the schools and colleges of which was included the Eclectic College, Ratledge System of Chiropractic Schools, the National College of Chiropractic of Chicago, Illinois, and the Los Angeles College of Chiropractic.

That affiant chose the Los Angeles College of

Chiropractic because after investigating the other schools above mentioned, it was his desire to become a general practitioner of the healing arts as taught in the Los Angeles College of Chiropractic. Further, after investigating all of the other colleges of chiropractic, he found that the Los Angeles College of Chiropractic taught the subjects that he [27] felt would fit him to become a general practitioner.

The course of instruction in the Los Angeles College of Chiropractic taken by affiant covered a 4,000-hour course. Affiant has examined a copy of the list of instruction given as set forth in Exhibit "B" of the affidavit of Dr. Harold A. Houde, D.C., and herein states that the same instruction was offered and taken in part for which affiant received the degree of Doctor of Chiropractic.

On attendance, affiant received instruction on the subjects and hours as listed in the transcript of his record which is marked Exhibit "A" and attached hereto. In addition thereto, affiant received the degree of Doctor of Naturopathy (N.D.) by diploma dated May, 1924, and subsequently, the degree of Philosopher of Chiropractic (PH C.).

The course of instruction taken and subsequently used by affiant in his practice was methods embodied in physiotherapy including electro, hydro, and mechanical therapies, together with general massage.

That the term chiropractic as known and used at the time of passage of the Chiropractic Act of 1922

was not limited to the definition as advocated by B. J. Palmer but had advanced to include spinal manipulation together with other drugless and physiological therapy including physiotherapy.

That among other textbooks studied by affiant while attending the Los Angeles College of Chiropractic was the "Principles and Practice of Spinal Adjustment" by Arthur L. Forster published at Chicago, the National School of Chiropractic, copyright 1915.

That affiant was a member of the State Board of Chiropractic Examiners from approximately 1930 to 1933; that the examinations prescribed by said Board to be taken by applicants for licenses to practice chiropractic have at all times included questions both on theory and the practice of physio therapy, including electro, mechanical, hydro, manipulation, etc. [28]

Of the various schools of chiropractic, the definition of chiropractic as adopted by the California Act of 1922 and as taught in the majority of California colleges of chiropractic was the broad Forster definition of chiropractic practice and not a limited technique of spinal adjustment.

That affiant was present in California and advocated and worked for the passage of the Chiropractic Act of 1922; that affiant procured from the Secretary of State, Frank M. Jordan, a copy of the sample ballot including the explanation of the Act and arguments for and against the passage of said

Act, a photostatic copy of which is attached hereto and marked Exhibit "B".

/s/ LEE H. NORCROSS, D.C., Affiant
Doctor of Chiropractic

Subscribed and sworn to before me this 19th day of November, 1954.

[Seal] /s/ JACK E. HILDRETH,
Notary Public in and for said
County and State [29]

[Endorsed]: Filed November 22, 1954.

[Title of District Court and Cause.]

AFFIDAVIT OF DR. HAROLD A. HOUDE, D.C.

State of California,
County of Los Angeles—ss.

Dr. Harold A. Houde, D.C., being first duly sworn, deposes and says:

That affiant was continuously a student at the Los Angeles College of Chiropractic from October of 1920 up to and including September of 1922; that the course of instruction received by affiant is contained in the photostatic copy of the transcript of his record which is attached hereto marked Exhibit "A"; a photostatic copy of the course of instruction covering 4,000 hours as was offered to students of the Los Angeles College of Chiropractic from October, 1920 up to and including January,

1924 is attached hereto and marked Exhibit "B".

The course of instruction taken and subsequently used by affiant in his practice was methods embodied in physiotherapy including electro, hydro, and mechanical therapies, together with general massage.

That the term chiropractic as known and used at the time of [39] passage of the Chiropractic Act of 1922 was not limited to the definition as advocated by B. J. Palmer but had advanced to include spinal manipulation together with other drugless and physiological therapy including physiotherapy.

That among other textbooks studied by affiant while attending the Los Angeles College of Chiropractic was the "Principles and Practice of Spinal Adjustment" by Arthur L. Forster published at Chicago, the National School of Chiropractic, copyright 1915.

Of the various schools of chiropractic, the definition of chiropractic as adopted by the California Act of 1922 and as taught in the majority of California colleges of chiropractic was the broad Forster definition of chiropractic practice and not a limited technique of spinal adjustment. That in 1922 the special brand of chiropractic that was taught by the Palmer school was not uniformly adopted by the schools and colleges teaching chiropractic in the State of California and elsewhere. A photostatic copy of the Los Angeles College of Chiropractic brochure of 1921-1922 outlining the scope, curriculum and general information is marked Exhibit "C" and attached hereto.

That the Palmer theory of chiropractic was limited to a "chiropractic thrust" and did not even embody the manipulation as taught in most schools and colleges.

At the time of passage of the Chiropractic Act there were several theories or schools as to what was the manner to practice chiropractic. That affiant chose to attend the Los Angeles College of Chiropractic because it offered education in the broad field of chiropractic.

/s/ HAROLD A. HOUDE, D.C., Affiant,
Doctor of Chiropractic

Subscribed and sworn to before me this 19th day of November, 1954.

[Seal] /s/ JACK E. HILDRETH,
Notary Public in and for said
County and State [40]

[Endorsed]: Filed November 22, 1954.

[Title of District Court and Cause.]

AFFIDAVIT OF
DR. CARL ERIC HOTCHKISS, D.C.

State of California,
County of Los Angeles—ss.

Dr. Carl Eric Hotchkiss, D.C., being first duly sworn, deposes and says:

That affiant enrolled in the Eclectic College of Chiropractic June 1, 1920 and graduated June 1,

1921; that he continued in post-graduate attendance until December 20, 1921; a true transcript of his curriculum, including the hours and subjects taken, is contained in the transcript of record, marked Exhibit "A" and attached hereto.

That among the subjects taught at the Eclectic College of Chiropractic from June, 1920 to and including the effective date of the Chiropractic Act, December 21, 1922, were:

Chiropractic Theory and Technique, Psycho-Analysis.

Osteopathic Theory and Technology, Obstetrics, Gynecology, Minor Surgery.

Diagnosis, Dermatology, Genito-Urinary Diseases.

Histology, Bacteriology, Hygiene. [88]

Nose and Throat.

Physiology, Pathology.

Psychology.

Anatomy.

Massage, Hydro-Therapy.

Dietetics.

Mechano-Therapy.

Roentgenology, Electro-Therapy, Chemistry.

Optometry and Diseases of the Eye.

That upon becoming interested in pursuing the chiropractic profession, affiant visited various schools of chiropractic, including the Los Angeles College of Chiropractic, Ratledge System of Chiropractic Schools, and Eclectic College of Chiropractic; that a photostatic copy of the brochure of the Eclectic College of Chiropractic which was given to affiant on his original interview in 1920 is attached

hereto and marked Exhibit "B"; that affiant chose the Eclectic College of Chiropractic because its curriculum offered an opportunity for affiant to obtain a broad scope of training in the field of chiropractic and allied subjects and was not limited to the B. J. Palmer concept of curing all ills and diseases by spinal manipulation only.

That upon graduating from the Eclectic College of Chiropractic on June 1, 1921, affiant received the degree of Doctor of Chiropractic (D.C.); that subsequently in 1921, affiant received the degree of Philosopher of Chiropractic (Ph.C.) and the degree of Doctor of Naturopathy (N.D.).

That among other textbooks studied by affiant while attending the Eclectic College of Chiropractic was the "Principles and Practice of Spinal Adjustment" by Arthur L. Forster published at Chicago, the National School of Chiropractic, copyright 1915.

That the theory and definition of chiropractic in 1922 had changed from B. J. Palmer's theory of curing all disease by spinal manipulation to one of the use of spinal adjustment together with drugless and physiological therapy such as attention to diet, hydrotherapy, massage, etc.

Of the various schools of chiropractic, the definition of [89] chiropractic as adopted by the California Act of 1922 and as taught in the majority of California colleges of chiropractic was the broad Forster definition of chiropractic practice and not a limited technique of spinal adjustment.

That at the time the 1922 Chiropractic Act was passed by initiative the great majority of chiro-

practors then practicing without a license or under Drugless Practitioners' licenses which were issued pursuant to the Medical Practice Act, had adopted and were practicing chiropractic in the broad sense of the word including the use of an adjunctive therapy which included what we now know as physiotherapy.

/s/ CARL ERIC HOTCHKISS, Affiant,
Doctor of Chiropractic

Subscribed and sworn to before me this 19th day of November, 1954.

[Seal] /s/ JACK E. HILDRETH,
Notary Public in and for said
County and State [90]

[Endorsed]: Filed November 22, 1954.

[Title of District Court and Cause.]

AFFIDAVIT OF A. SCHLESSING

A. Schlessing, being duly sworn upon his oath, states that he is President of A. Schlessing & Co., a corporation, and that upon the institution of this action he immediately went to California and the Company undertook voluntarily the defense of this action on behalf of the various owners of the machines under seizure; that counsel were employed by the company in Los Angeles, in addition to counsel in St. Louis. As a result of negotiations with government counsel, a consent decree was entered into as

reflected in the record of this proceeding. Thereafter, A. Schlessing & Co. employed the firm of Scientific Associates, Inc., a St. Louis concern, for the purpose of conducting experiments to demonstrate the safety and therapeutic value of the machine. Extensive negotiations were carried on with the Food and Drug Administration, Washington, D. C., and affiant made one trip personally to Washington for this purpose and affiant's counsel made two trips to Washington, accompanied by a representative of Scientific Associates. Reports of the work performed by Scientific Associates were submitted to Washington demonstrating the safey of the device. The mechanics of the device were reviewed with representatives of the Food & Drug Administration and agreement reached as to installation of additional safety controls on the devices so as to [108] better control the output of energy and length of treatment with the result that the mechanical design and operation of the device was approved. Machines were placed in various hospitals and clinics in St. Louis, Chicago and East St. Louis, Illinois, and with physicians in St. Louis and Chicago, for the purpose of determining the therapeutic value of the machine. As a result of these efforts a report was prepared by Dr. A. H. Diehr, Chief of the Service Department of Orthopedics and Director of the Department of Rehabilitation, Missouri Baptist Hospital, St. Louis, Roland M. Klemme, M.D., St. Louis, Missouri, and F. M. Younger, B.S., St. Louis, Missouri, on the indications for the use of the Schlessing Ultrasoniseur,

which report was submitted to Washington. The directions for the use of the Schlessing Ultrasoniseur were revised and a number of drafts prepared and submitted to Washington until finally, in July of 1953, a draft was approved by Washington and the Food and Drug Administration authorized distribution of the reworked and relabeled devices to practitioners licensed by law to use ultrasonic devices. At this point A. Schlessing & Co., which had voluntarily ceased distribution of its devices upon the institution of the condemnation action, resumed the distribution of the devices, having been totally out of business for almost a year. At this time also the Company proposed to return the devices under seizure to their respective owners but was confronted with the proposition that the Food and Drug Administration would not permit the return of such machines as were owned by chiropractors on the ground that chiropractors in California were not authorized to use such devices. Counsel for the Company argued and briefed this point with the Food and Drug Administration but were unable to reach any agreement as to the law, so that this question is now being presented to the Court for decision. The Company has been seriously handicapped in its business by reason of the extended proceedings, it being now almost two full years since the institution of the action, and the Company has been able to resume operations only to a limited extent since it felt that it could not, in good conscience, resume full scale operations as long as the California machines remained under

seizure. At the present time the devices under seizure are in St. Louis for the purpose of installation [109] of safety controls. These modifications have been performed on some of the devices and approved by the local office of the Food and Drug Administration, but the work has been suspended pending the decision as to whether or not the machines can be returned to their owners since there would be no point in expending further moneys on the machines if they must be turned back to the marshal for destruction.

/s/ A. SCHLESSING

Subscribed and Sworn to before me this 15th day of July, 1954.

[Seal] /s/ MARIE G. SHAW,
Notary Public [110]

[Endorsed]: Filed November 22, 1954.

[Title of District Court and Cause.]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

The above entitled matter having come on for hearing on December 22, 1954, on a Motion by Claimant A. Schlessing to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure, the Libelant United States of America, being represented by Laughlin E. Waters, United States Attorney, Max

F. Deutz, Assistant United States Attorney, and Arthur A. Dickerman, Attorney, Department of Health, Education and Welfare, and Claimant A. Schlessing being represented by Spencer E. Van Dyke and Jack E. Hildreth, and the Court having granted a Motion by the National Chiropractic Association, by C. P. Von Herzen and S. L. Laidig, Esquires, to appear Amicus Curiae, and the Court having [111] accepted Stipulations of Fact, and having received arguments both written and oral, and the Court being fully satisfied in the premises, and it appearing to the Court that:

(1) On September 5, 1952, the United States, libelant herein, filed a Libel of Information in this Court under the Federal Food, Drug, and Cosmetic Act seeking condemnation of 75 devices, more or less, designated as "The Schlessing Ultrasoniscur" which had been shipped in interstate commerce from St. Louis, Missouri, to various chiropractors practicing within the jurisdiction of this Court.

(2) The Libel alleged that these devices were misbranded in violation of 21 U.S.C. 352(a) because their labeling bore false and misleading therapeutic claims for many disease conditions ranging from abscesses to ulcers.

(3) The Libel alleged that these devices were further misbranded in violation of 21 U.S.C. 352 (a) because their labeling contained such false and misleading statements as "This Machine Is Absolutely Safe"; "No special skill, no involved instructions and no long experience is necessary to use the Schlessing Ultrasoniscur properly"; and "There are

no contraindications. No danger of deep burns, tissue damage or irritation. Equally important, there are no possible harmful effects to the person administering treatment."

(4) The Libel also alleged that the devices were misbranded in violation of 21 U.S.C. 352(f)(1) because their labeling failed to bear adequate directions for use.

(5) The Libel also alleged that the devices were adulterated in violation of 21 U.S.C. 351(c) because their strength differed from and their quality fell below that which they purported and were represented to possess, since their ability to produce total [112] sound output differed materially from the ability they were represented to possess, and the output meter did not accurately gauge the energy density output of the devices.

(6) On October 22, 1952, Mr. A. Schlessing of St. Louis, Missouri, intervened as claimant in this proceeding. He is the president of A. Schlessing and Company, Inc., which manufactured these devices. He is also the agent of the owners and consignees of the devices.

(7) Also on October 22, 1952, a Consent Decree of Condemnation was entered in this case. By its terms, the devices under seizure were adjudged adulterated and misbranded as alleged in the Libel and were condemned under 21 U.S.C. 334(a). In addition, pursuant to 21 U.S.C. 334(d), claimant was accorded the privilege of attempting to bring the devices into compliance with law under supervision of a duly authorized representative of the Federal

Security Administrator, hereinafter called the Secretary.[1]

(8) One provision in the Consent Decree declares in substance that the claimant shall not distribute the devices until he obtains a written release from a representative of the Secretary, and there is the further proviso that

"Claimant shall make no distribution of said articles or any part of them except in strict accord with such terms and conditions as may be included in said written release." [113]

(9) Claimant thereupon arranged to ship the 47 devices actually seized by the United States Marshal back to his place of business at St. Louis, Missouri, where six of them were reconditioned from a physical standpoint to the satisfaction of the Department of Health, Education, and Welfare. Reconditioning of the remaining 41 devices has been suspended until a final decision is reached regarding the legality of claimant's proposed method of distribution of the six reconditioned devices.

(10) Claimant now wishes to ship the six reconditioned devices back to the licensed California

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[1] The Federal Security Administrator was then the head of the Federal Security Agency which was charged with the administration of the Federal Food, Drug, and Cosmetic Act. On April 11, 1953, pursuant to Reorganization Plan No. 1 of 1953 and 67 Stat. 18, the Federal Security Agency was abolished and the Department of Health, Education, and Welfare was established to administer the functions formerly in that Agency, under the supervision and direction of the Secretary of that Department. [18 Fed. Reg. 2053].

chiropractors in whose possession these devices were seized at the outset of this proceeding. The Department has refused to release the devices for such distribution.

(11) It is agreed by the parties that these ultrasonic devices produce high frequency sound waves which have theropeutic value as an adjunct in the treatment of osteoarthritis and bursitis. It is also agreed—

"Ultrasonic therapy cannot be employed safely and efficaciously by the layman in self-medication, but requires competent supervision in its administration. Adequate directions for unsupervised lay use cannot be written for ultrasonic devices, within the meaning of 21 U.S.C. 352(f)(1). Interstate distribution which would not violate the Federal Food, Drug, and Cosmetic Act must therefore comply with the regulations which exempt devices from bearing adequate directions for use in their labeling. [21 C.F.R. §1.106, as amended]. One provision of these regulations exempts a device which is shipped to 'a practitioner licensed by law to * * * use or direct the use of the device.' [21 C.F.R. §1.106(e)]." [114]

(12) The Department's refusal to release the reconditioned devices for distribution in the manner proposed by the claimant is based upon its view that California chiropractors are not licensed by law to use or direct the use of ultrasonic devices. Consequently, shipment of the devices to the chiropractors would not meet the conditions of the ex-

emption regulations.[2] Since the devices would not bear adequate directions for use in their labeling as required by 21 U.S.C. 352(f)(1), and would not be exempt from that requirement, they would be misbranded.

(13) On May 24, 1954, claimant filed a Motion to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices under Seizure. The Motion asserts that the Department's refusal to approve is based upon an erroneous interpretation of the scope of a license granted under the California Chiropractic Act.

Now Therefore, the Court makes the following:

Findings of Fact

I.

Chiropractic is a system for the practice of adjusting the joints, especially at the spine, by hand, for the treatment of disease and ailments. [115]

II.

Ultrasonic therapy is taught in one chiropractic college in California, but it is not a part of the practice of chiropractic.

III.

A subject does not become a part of the practice of chiropractic merely because it is taught in a

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[2] Paragraph (7) of the Consent Decree of Condemnation declares: "The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State * * * in which they are sold or disposed of."

chiropractic college. Many subjects are taught in Chiropractic colleges which are not part of the practice of chiropractic.

IV.

Ultrasonic therapy is not a necessary mechanical measure incident to the care of the body in the practice of chiropractic.

V.

Ultrasonic therapy is a part of the practice of medicine.

VI.

A chiropractor licensed under the laws of California is not authorized to use or direct the use of the ultrasonic devices under seizure in this case.

From the foregoing Findings of Fact the Court makes the following

Conclusions of Law

I.

Devices which are condemned for violation of the Federal Food, Drug, and Cosmetic Act may be salvaged by the claimant pursuant to 21 U.S.C. 334 (d), not as a matter of right but within the discretion of the Court. Salvaging, where authorized by the Court, must be carried out under the supervision of an officer or employee duly designated by the Secretary of Health, Education, and Welfare.

II.

Salvaging of condemned devices cannot be authorized under 21 U.S.C. 334(d) in a manner that will violate the Federal Food, [116] Drug, and

Cosmetic Act or the laws of the State in which they are sold.

III.

Under 21 U.S.C. 352(f)(1), a device is misbranded if its labeling does not bear adequate directions for use.

IV.

Where a device cannot be employed safely and efficaciously by the layman in self-medication but requires competent supervision in its administration, "adequate directions for use" cannot be written within the meaning of 21 U.S.C. 352(f)(1).

V.

A device may be exempt from the requirement that its labeling bear "adequate directions for use" if it complies with the exemption regulations promulgated by the Secretary of Health, Education, and Welfare under 21 U.S.C. 352(f).

VI.

A device which is shipped to "a practitioner licensed by law to * * * use or direct the use of the device" may be exempt from the requirement that its labeling bear "adequate directions for use." [21 C.F.R. §1.106(e)].

VII.

A chiropractor licensed under the California Chiropractic Act is authorized (a) to practice chiropractic as taught in chiropractic schools or colleges and (b) to use all necessary mechanical, and hygienic and sanitary measures incident to the

care of the body, but not to practice medicine, surgery, osteopathy, dentistry, or optometry, and not to use any drug or medicine included in materia medica. [117]

VIII.

The term "necessary mechanical * * * measures incident to the care of the body" as used in Section 7 of the California Chiropractic Act further delineates the scope of a licentiate's authority to assure his right to use only such measures as are necessary and incidental to the care of the body in the practice of chiropractic, such as a chiropractic table.

IX.

Ultrasonic therapy is a part of the practice of medicine; it is not a part of the practice of chiropractic nor is it a "necessary mechanical * * * measure incident to the care of the body" as that term is used in Section 7 of the California Chiropractic Act.

X.

The ultrasonic devices under seizure in this case do not bear adequate directions for use and are not exempt from that requirement.

XI.

A chiropractor licensed under the California Chiropractic Act is not "a practitioner licensed by law to use or direct the use of" the ultrasonic devices under seizure.

XII.

Claimant's Motion should be denied with leave to the claimant to submit to the Department of Health,

Education, and Welfare any [118] other proposal for distribution that would place these devices in the hands of practitioners who are licensed by law to use them.

Dated: February 9, 1955.

/s/ WM. M. BYRNE,
United States District Judge [119]

[Endorsed]: Filed February 10, 1955.

In the United States District Court for the Southern District of California, Central Division

Civil No. 14482-WB

UNITED STATES OF AMERICA,
Libelant,

vs.

75 Articles of device, more or less, designated as "The Schlessing Ultrasoniscur," together with their labeling, Respondents.

ORDER

The above entitled matter having come on for hearing on December 22, 1954, on a Motion by Claimant A. Schlessing to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure, the Libelant United States of America being represented by Laughlin E. Waters, United States Attorney, Max F. Deutz, Assistant United States Attorney, and Arthur A. Dickerman, Attorney, Department of

Health, Education, and Welfare, and Claimant A. Schlessing being represented by Spencer E. Van Dyke and Jack E. Hildreth, and the Court having granted a Motion by the National Chiropractic Association, by C. P. Von Herzen and S. L. Laidig, Esquires, to appear Amicus Curiae, and the Court having [120] accepted Stipulations of Fact, and having received arguments both written and oral, and the Court being fully satisfied in the premises, and the Court having made and filed its Findings of Fact and Conclusions of Law.

Now Therefore, It Is Hereby Ordered that the Motion of Claimant to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure is denied, with leave to the claimant to submit to the Department of Health, Education, and Welfare any other proposal for distribution that would place these devices in the hands of practitioners who are licensed by law to use them, providing such proposal is submitted to the Department of Health, Education, and Welfare, or its field representatives, within a period of 90 days from the entry of this Order.

Dated: February 9, 1955.

/s/ WM. M. BYRNE,
United States District Judge [121]

Affidavit of Service by Mail attached. [122]

[Endorsed]: Judgment entered and filed February 10, 1955.

[Title of District Court and Cause.]

NOTICE OF APPEAL

Notice is hereby given that A. Schlessing, the Claimant herein, hereby appeals to the Circuit Court of Appeals for the Ninth Circuit from the Order denying claimant's motion to compel administrative approval of Claimant's Proposed Method of Distributing Devices under Seizure, entered in this action on February 10, 1955.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By JACK E. HILDRETH [123]

Affidavit of Service by Mail attached. [124]

[Endorsed]: Filed April 7, 1955.

In the United States District Court for the Southern District of California, Central Division

Civil No. 14482-WB

UNITED STATES OF AMERICA,
Libelant,

vs.

75 Articles of Device, Etc., Respondents,

FINAL DECREE

This Court, having heretofore issued a Consent Decree of Condemnation on October 22, 1952, wherein said Consent Decree of Condemnation provided that the articles of device under seizure were

adulterated and misbranded as alleged in the Libel of Information in violation of 21 U.S.C. 351(c), 352(a), and 352(f)(1); and having ordered said devices condemned pursuant to 21 U.S.C. 334(a); and having further ordered that the United States recover from the claimant court costs and fees, pursuant to 21 U.S.C. 334(e); and having further ordered that the United States Marshal deliver all of the literature accompanying said devices to the representative of the United States Food and Drug Administration; and having further ordered that the United States Marshal release the said devices (without the said literature) to the custody of the claimant for the purpose of attempting to bring the said articles into compliance with the law, under the supervision of the United States Food and Drug Administration; and the Court having further entered its order on February 10, 1955, denying the claimant's motion which, if granted, would have permitted distribution of the devices to chiropractors in California, [127] granting, however, to the claimant a period of ninety days within which to submit to the Department of Health, Education, and Welfare any other proposal for distribution; and said ninety days having elapsed, and the court having been advised by the parties that the claimant has made no additional proposal for distribution and chooses to stand upon the proposal which was rejected by the aforesaid order;

Now, Therefore, It Is Hereby Ordered, Adjudged and Decreed:

(1) That the claimant return said devices at his

own expense to the United States Marshal for this District, under the supervision of the St. Louis District of the Food and Drug Administration, Department of Health, Education, and Welfare, Room 1007 New Federal Building, 1114 Market Street, St. Louis 1, Missouri; and

(2) That the United States Marshal shall offer said devices for sale in such manner and under such conditions as shall be approved by the Los Angeles District of the Food and Drug Administration, Department of Health, Education and Welfare; and

(3) That Venditioni Exponas issue therefor, and that said United States Marshal make his return thereof into Court, after deducting all expenses incident to said sale.

Dated: May 17, 1955.

/s/ WM. M. BYRNE,
United States District Judge

Presented by:

MAX F. DEUTZ, Asst. U. S. Attorney,
Attorney for Libelant.

Approved as to Form:

/s/ JACK E. HILDRETH,
Attorney for Claimant. [128]

[Endorsed]: Filed May 17, 1955.

[Endorsed]: Judgment entered May 18, 1955.

[Title of District Court and Cause.]

ORDER STAYING FINAL DECREE, REDUCING BOND, AND PERMITTING REMOVAL OF DEVICES

The claimant having informed the Court that he intends to appeal from the Final Decree, heretofore ordered in this case on May 17, 1955; and the parties having agreed to the entry of an Order Staying said Final Decree;

Now, therefore, It Is Hereby Ordered:

(1) That the Final Decree be stayed during the pendency of the appeal in this proceeding;

(2) That the $30,000.00 performance bond which was posted by the claimant, pursuant to the Consent Decree of Condemnation filed in this cause on October 22, 1952, may be reduced to $5,000.00, which bond shall incorporate the same terms and conditions as the $30,000.00 bond as aforesaid:

(3) That upon the claimant's filing of a good and sufficient $5,000.00 performance bond with surety, as aforesaid, the $30,000.00 bond already on file shall be exonerated; and

(4) That the claimant may, with the prior written approval [129] of the St. Louis District, Food and Drug Administration, Department of Health, Education and Welfare, 1114 Market Street, St. Louis 1, Missouri, remove the devices under seizure in this case from his place of business to a warehouse.

Dated: May 17, 1955.

/s/ WM. M. BYRNE,
United States District Judge

We hereby agree to the entry of the foregoing Order:

/s/ JACK E. HILDRETH,
Attorney for Claimant
/s/ MAX F. DEUTZ,
Attorney for Libelant [130]

[Endorsed]: Filed May 17, 1955.

[Endorsed]: Judgment Docketed and Entered May 18, 1955.

[Title of District Court and Cause.]

NOTICE OF APPEAL

Notice is hereby given that A. Schlessing, the Claimant herein, hereby appeals to the Court of Appeals for the Ninth Circuit from the Final Decree entered in this action on May 17, 1955.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By JACK E. HILDRETH [131]

Affidavit of Service by Mail attached. [132]

[Endorsed]: Filed May 27, 1955.

[Title of District Court and Cause.]

CLERK'S CERTIFICATE

I, John A. Childress, Clerk of the United States District Court for the Southern District of California, do hereby certify that the foregoing pages numbered 1 to 133, inclusive, contain the original

Libel;

Claim of A. Schlessing;

Consent Decree of Condemnation;

Stipulation and Order Scheduling Further Court Proceedings;

Stipulation as to Issue;

Stipulation of Facts;

Motion to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure;

Affidavit of Dr. Lee H. Norcross, D.C.;

Affidavit of Dr. Harold A. Houde, D.C.;

Affidavit of Dr. Carl Eric Hotchkiss, D.C.;

Affidavit of A. Schlessing;

Findings of Fact and Conclusions of Law;

Order;

Notice of Appeal filed April 27, 1955;

Stipulation and Order Extending Time for Filing Record on Appeal and Docketing Appeal;

Final Decree;

Order Staying Final Decree, Reducing Bond, and Permitting Removal of Devices;

Notice of Appeal filed May 27, 1955;

Stipulation as to Record, which, together with a full, true and correct copy of the Reporter's Tran-

script of Proceedings had on November 22 and December 22, 1954; Respondent's exhibit "B"; Respondent's exhibit "A"; all in said cause, constitute the transcript of record on appeal to the United States Court of Appeals for the Ninth Circuit.

I further certify that my fees for preparing the foregoing record amount to $1.60, which sum has been paid by appellant.

Witness my hand and the seal of said District Court, this 29th day of June, 1955.

[Seal] JOHN A. CHILDRESS,
Clerk
/s/ By CHARLES E. JONES,
Deputy

[Title of District Court and Cause.]

TRANSCRIPT OF PROCEEDINGS

Los Angeles, Calif., Monday, Nov. 22, 1954

Honorable Wm. M. Byrne, Judge presiding.

* * * * *

Mr. Hildreth: If the Court please:

We are before this court again, pursuant to the Consent Decree of Condemnation wherein 47 devices in this matter were condemned and on certain conditions were returned to the manufacturer to bring them up to standards and correct labeling according to the Federal Food and Drug Acts.

We now propose to distribute these devices and

we feel that our proposal is in accordance with that Act.

Through stipulations and various discussions with the Federal authorities, Mr. Dickerman and Mr. Deutz, we have cut this issue down, we feel, to the most simplest possible terms, one, that is, if the chiropractors are entitled to use these devices, because of their licenses to practice chiropractic, in the state of California, then, the proposed distribution we feel is correct.

We have examined the authorities and we do now offer some new arguments, that we feel have not been presented to this court or to any other California court.

Our theory is different in this respect: We feel that these machines are therapeutic devices. As a matter of fact, I think the stipulation will go somewhat to that end.

These machines are machines that are essentially to put out massage to the tissue of the human body; that they are caliorated to put out one-half of a watt per square centimeter of the head, of the induction head and in that regard are not harmful.

In the Stipulation and in the labeling proposed by the Claimant at this time, there is appended Exhibit A. Exhibit A is our proposed labeling in some four pages and you will note in the Bibliography on page 4 there is reference to the effect of multiple treatments of New Zealand white rabbits, a study made by a group in St. Louis. We have a copy of this study, a laboratory analysis, and we

would like to lodge it at this time with the court and have that marked as an exhibit.

The Court: Pardon me. Is that offered for identification?

Mr. Hildreth: Yes, for identification, at this time.

The Clerk: It will be Respondents' Exhibit A, for identification.

(Said 4-page document was marked by the Clerk as Respondents' Exhibit A, for identification.)

Mr. Hildreth: Ultrasonic therapy is not something that is entirely new. It is a rather recent development in the field of the whole practice.

The device that we have manufactured is designed mainly for the use of the practicing physiotherapist, chiropractor, osteopath, physician, in conjunction with other forms of treatment of these diseases. It puts out, as I say, half a watt per square foot of the transducer head.

According to the various physical and medical journals, in the treatments used by it the physicians and surgeons have all stated that this device has therapeutic value.

The physician normally uses an output of energy from 3 to 6 watts per square foot of the transducer head. The authority for that we have cited in our reply brief, the statement from the Second Annual Conference on Physical Medicine.

The reason this machine has been cut down to the one-half watt per square foot is to take out any possibility that is possible of course of any harm or danger in its application.

This machine is used and intended for use solely in the treatment of two diseases, bursitis and osteoarthritis, and it is strictly one of massage.

The question then turns on whether or not a chiropractor may use physiotherapeutic devices. We submit that he can.

In 1922 the field of chiropractic had only been some 18 years old.

Regarding the factual background of chiropractic, although it was originally developed or discovered perhaps by Dr. D. D. Palmer, who incidentally I believe was a medical doctor, he did not bring that science into being as we now know it, but he waited until his son, Dr. B. J. Palmer in 1903 put forth the theory that all diseases could be cured by the manipulation of the spine.

By 1915, many doctors, medical doctors, osteopaths and others interested in the field of chiropractic had expanded and developed the field of chiropractic so that it did not merely include the cure of all diseases by manipulation of the spine by hand but included additional therapy to be used with the spinal adjustment.

In 1922, at the time of the Act, there were several schools of chiropractic, two or three of which were located in Southern California. One was the Eclectic College of Chiropractic here. Another was the Los Angeles College of Chiropractic, and the third was the Ratledge System of Chiropractic Schools.

The Eclectic College and the Los Angeles College did not prescribe to the theory that all diseases

could be cured by manipulation of the spine. They felt that adjunct therapy was also necessary. As a matter of fact, in their textbooks, the Chiropractors were taught that there were two diseases that the spinal manipulation would not cure. One was mental illnesses and the other being an osteomyelitis type of disease.

We also offer for identification a textbook used, according to the affidavits on file, entitled Principles and Practice of Spinal Adjustment, by Arthur L. Forster, M.D., D.C., published in Chicago by The National School of Chiropractic, Copyright, 1915.

The Clerk: Exhibit B, for identification.

(Said book was marked by the Clerk as Respondents' Exhibit B for identification.)

* * * * *

December 22, 1954

Mr. Hildreth: If the Court please, at the conclusion of the hearing in the early part of this month, I was discussing the warranties of this machine very briefly.

As the Court will recall, the machine involved in this action is one of an ultrasonic vibrating type that is calibrated to put out one-half a watt of energy per square centimeter of the transducer head. This is a rather new type of therapy, developed primarily in Europe, but since 1937 some of the medical doctors, osteopaths and chiropractors have been in some ways experimenting with it.

They have now the American Institute of Ultrasonics in Medicine, and this is the "Scientific Pro-

ceedings of the Second Annual Conference of Ultrasonic Therapy," reprinted from the American Journal of Physical Medicine, Volume 33, No. 1, February, 1954. Dr. Karl Theo Dussik delivered a paper before that body, and at that time, on page 11 of the document I have described, he states:

"Of great importance is the knowledge of the maximum intensity which is tolerated without producing a damaging effect. This threshold is well established. For practical use, intensities of not more than 3 watts per square centimeter can be considered as safe, provided a technique is used in which the treating head is in continual movement. Pain is the best practical safeguard; if no immediate pain is produced during the actual application, no damaging effect need be expected, provided of course that the exposed area has a normal pain sensation. In case of interrupted energy application (pulsed sound) a higher intensity is safe."

It is therefore submitted by the moving party in this instance that this machine, being one that has been calibrated at a lower point, it is one of the physiotherapy machines, and it has therapeutic value.

I think that is the main distinction between the case on which the government relies so heavily, and heard at some length in this court, namely, the Halox case, and this case. In the Halox case this Court had a machine that had no therapeutic value. As a matter of fact, the Court had affidavits, and one of the affidavits was produced by the same doctor,—I think it was Houde or Norcross, or one

of them, that has also been produced in this case, stating that ultrasonic therapy has never been taught in the School of Chiropractic in the State of California.

So with this in mind, I think we should turn to the question of what the law allows a chiropractor to do in the State of California. The courts have held, from People vs. Steele on, that it limits the chiropractor to that which was taught in the schools of chiropractic in 1922. They further state the Court should take evidence to find out what was taught at that time.

In 1922, according to the affidavits of Drs. Norcross and Houde, the book used in the Eclectic College of Chiropractic was the "Principles and Practice of Spinal Adjustment" by Arthur L. Forster, this being Exhibit B, for identification, and if the Court will go through this, the Court will find that the treatment prescribed by Dr. Forster embodies the use of physiotherapy in nearly three-fourths of the matters therein set forth to be treated. As an example, rheumatics, in chronic articular rheumatism, the treatment, including some adjustment, includes:

"Baking of the joints or application of heat in various ways: hot air, electricity, or steam baths are very useful. The diet should be free from meat, and only fresh vegetables should be used."

Going on to rheumatoid arthritis the court would find that the treatment also includes the use of heat, baths, hot compresses, massage—a very im-

We submit that at this time of the doctors that are using this machine in accordance with their license, of the 47 machines—and I do not have an affidavit, but I have checked it—I have only to say to the Court that there are some 40 of them that are licensed M.D.s or naturopaths.

I think that if the Court, after reading the book, and which I will offer in evidence at this time, together with Exhibit 1, as showing and describing what the affidavits state,——

The Clerk: That is Exhibit A.

Mr. Hildreth: Is that A?

The Clerk: Yes.

Mr. Hildreth: ——Exhibits A and B,—that if the Court follows the archaic definition of a chiropractic as merely the spinal adjustment, the manipulation of the spine with the hand, that the Oosterveen case is then left meaningless, and that the Evans vs. McGranaghan case is within that category, wherein they state the Court must find out just exactly what was taught.

I think further in the case of People vs. LaBarre the Court stated it was necessary to determine at that time what was taught in the school of chiropractic at this time.

If the Court will go through the affidavits, you will find that physiotherapy was taught throughout that era as a part of chiropractics. Another thing, that when the Act was amended in 1947 it increased the requirements to 4,000 hours from 2,400 hours, and you will note that the division wherein physiotherapy was actually spelled out is the division on

chiropractic, and that, therefore, the two have been associated together so closely in the minds of everyone that there be physiotherapy at that point in the requirements.

In Hunt vs. State Board I think that the Court made a very sage observation, that the healing arts are not a static science, that they must be able to advance, and if the narrow limited view is followed by the Court that a chiropractor is limited to the adjustment of the spine, with all due respect, I cannot see how any adjustment or any advancement can be made in the field of chiropractic.

I further feel, under the cases as they now stand, that the field of chiropractic has advanced to a point where the doctors have a much better education, that the stigma which was attached to them back in 1920 or 1922, when they were arrested and thrown in jail, has gone, and that their proper place in the healing arts, which is manipulation and adjustment and replacing of joints, and the physiotherapeutic devices which they need in that field should be allowed to them in the practice of their healing arts.

Thank you.

Mr. Deutz: Your Honor, I believe that the government in this case has briefed its position at length, so I do not feel that oral argument on our part is called for.

We feel that the libelant's reply brief in essence answers the argument given today. In fact, it was prepared after this argument was commenced at the last session of this Court in this matter, and unless

the Court has some particular inquiry as to the government's position, we intend to rely on the briefs as filed, and, particularly, on the interpretation of the scope of the practice of chiropractics, as set forth in the authorities, and as decided by this Court in the Halox case. And we have pointed at some length in our libelant's reply brief to the actual catalogs or manuals from the various school of chiropractics to show by their own language that they call for the actual practice of chiropractics to include only the manipulation of the spine or the body by hand, and that the other things that were taught in the schools of chiropractics were for the purpose of a well-rounded education, so that the chiropractor might know the limits of his practice, and might know the limits of his powers of healing, but that they did not enlarge the field of chiropractics itself, and that among those things was the field of physical therapy, in which this particular machine arises.

* * * * *

Mr. Hildreth: As a matter of record, if the Court please, Exhibits A and B were offered. Were they received?

The Court: They are offered at the present time in evidence?

Mr. Deutz: We are not going to object, your Honor. We doubt very much their weight as evidence in this case, but we won't object to their being in evidence.

The Court: They will be received.

(Thereupon the documents, heretofore marked Respondents' Exhibits A and B, were received in evidence.)

The Court: The matter will stand submitted.

[Endorsed]: No. 14802. United States Court of Appeals for the Ninth Circuit. A. Schlessing, claimant of 75 articles of device, more or less, designated as "The Schlessing Ultrasoniscur", together with their labeling, Appellant, vs. United States of America, Appellee. Transcript of Record. Appeal from the United States District Court for the Southern District of California, Central Division.

Filed: June 30, 1955.

/s/ PAUL P. O'BRIEN,
Clerk of the United States Court of Appeals for the Ninth Circuit.

In the United States Court of Appeals
for the Ninth Circuit

No. 14802

A. SCHLESSING, Appellant,

vs.

UNITED STATES OF AMERICA, Appellee.

APPELLANT'S STATEMENT OF POINTS

The Appellant, in accordance with Rule 17 (6), hereby sets forth the following statement of points which are concerned in this appeal.

The Appellant contends that the United States District Court erred in the following particulars:

(1) In not granting Appellant's motion for administrative approval of Appellant's proposed method of distributing the devices under seizure.

(2) In holding that the practice of chiropractic is limited to the definition:

"Chiropractic is a system for the practice of adjusting the joints, especially at the spine, by hand, for the treatment of disease and ailments."

(3) In holding that:

"Ultrasonic therapy * * * is not a part of the practice of chiropractic."

(4) In holding that the practice of chiropractic is a stationary science and the scope of practice is not expanded by scientific developments and increasing educational requirements and subjects taught in schools of chiropractic.

(5) In holding that:

"Ultrasonic therapy is not a necessary mechanical measure incident to the care of the body in the practice of chiropractic."

(6) In holding that the practice of medicine is not permitted as a part of the practice of chiropractic under the California Chiropractic Act.

(7) In holding that:

"A chiropractor licensed under the laws of California is not authorized to use or direct the use of the ultrasonic devices under seizure in this case."

(8) In holding that:

"The term 'necessary mechanical * * * measures incident to the care of the body' as used in Section 7 of the California Chiropractic Act further delineates the scope of a licentiate's authority to assure his right to use only such measures as are necessary and incidental to the care of the body in the practice of chiropractic, such as a chiropractic table."

(9) In holding that:

"Ultrasonic therapy is a part of the practice of medicine; it is not a part of the practice of chiropractic nor is it a 'necessary mechanical * * * measure incident to the care of the body' as that term is used in Section 7 of the California Chiropractic Act."

(10) In holding that:

"The ultrasonic devices under seizure in this case do not bear adequate directions for use and are not exempt from that requirement."

(11) In holding that there is no evidence before the court in support of the findings of fact.

(12) In holding that the evidence does not support the conclusions of law.

Dated: This 8th day of July, 1955.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By SPENCER E. VAN DYKE,
Attorneys for Appellant

Affidavit of Service by Mail attached.

[Endorsed]: Filed July 11, 1955. Paul P. O'Brien, Clerk.

[Title of U. S. Court of Appeals and Cause.]

STIPULATION CONCERNING DESIGNATION OF THE RECORD FOR PRINTING (Civil Rule 17(6))

It Is Hereby Stipulated by the parties to this appeal, through their respective counsel, as follows:

A. The material portions of the record in the above-entitled action are hereby designated for printing and include:

1. Libel of Information.
2. Claim of A. Schlessing.
3. Consent Decree of Condemnation.
4. Stipulation and Order Scheduling Further Court Proceedings.
5. Stipulation as to Issue.

6. Stipulation of Facts (including Exhibit A).

7. Motion to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure.

8. Supplemental Stipulation as to Facts.

9. Affidavit of Dr. Lee H. Norcross, D.C. (except attached exhibits).

10. Affidavit of Dr. Harold A. Houde, D.C., (except attached exhibits).

11. Affidavit of Dr. Carl Eric Hotchkiss, D.C. (except attached exhibits).

12. Affidavit of A. Schlessing.

13. Findings of Fact and Conclusions of Law.

14. Order.

15. Notice of Appeal (filed April 7, 1955).

16. Final Decree.

17. Order Staying Final Decree, Reducing Bond, and Permitting Removal of Devices.

18. Notice of Appeal (filed May 27, 1955).

19. Reporters' Transcript of Oral Proceedings, except that the following material shall not be printed: Page 1, lines 1 through 12; page 1, lines 16 through 26; page 2, lines 1 through 9; page 3, lines 1 through 25; page 4, lines 1 through 5; page 8, lines 16 through 25; page 9, lines 1 through 25; page 10, lines 1 through 25; page 11, lines 1 through 9; page 19, lines 1 through 3; page 20, lines 1 through 21.

B. It Is Further Stipulated, subject to the approval of the court, that the following exhibits which are a part of the record on appeal, certificated by the District Court, shall not be printed but

shall be presented to the court for consideration in said appeal in their original form:

1. Exhibits A and B, identified in and attached to the Affidavit of Dr. Lee H. Norcross, D.C.

2. Exhibits A, B, and C, identified in and attached to the Affidavit of Dr. Harold A. Houde, D.C.

3. Exhibits A and B, identified in and attached to the Affidavit of Dr. Carl Eric Hotchkiss, D.C.

4. The report entitled, "Effect of Single and Multiple Treatments on New Zealand White Rabbits with a Schlessing Ultrasoniseur", identified in the Reporters' Transcript of Oral Proceedings as Claimant's Exhibit A (R. T. page 5, lines 19 through 25).

5. The volume entitled "Spinal Adjustment" by Forster, (1915), identified in the Reporters' Transcript of Oral Proceedings as Claimant's Exhibit B (R. T. page 8, lines 8 through 15).

Dated: This 7th day of July, 1955.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By SPENCER E. VAN DYKE,
Attorneys for Appellant
LAUGHLIN E. WATERS,
United States Attorney
/s/ By MAX F. DEUTZ,
Asst. U. S. Attorney, Chief of Civil Division,
Attorneys for Appellee

[Endorsed]: Filed July 11, 1955. Paul P. O'Brien, Clerk.

6. Stipulation of Facts (including Exhibit A).

7. Motion to Compel Administrative Approval of Claimant's Proposed Method of Distributing Devices Under Seizure.

8. Supplemental Stipulation as to Facts.

9. Affidavit of Dr. Lee H. Norcross, D.C. (except attached exhibits).

10. Affidavit of Dr. Harold A. Houde, D.C., (except attached exhibits).

11. Affidavit of Dr. Carl Eric Hotchkiss, D.C. (except attached exhibits).

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4. The report entitled, "Effect of Single and Multiple Treatments on New Zealand White Rabbits with a Schlessing Ultrasoniseur", identified in the Reporters' Transcript of Oral Proceedings as Claimant's Exhibit A (R. T. page 5, lines 19 through 25).

5. The volume entitled "Spinal Adjustment" by Forster, (1915), identified in the Reporters' Transcript of Oral Proceedings as Claimant's Exhibit B (R. T. page 8, lines 8 through 15).

Dated: This 7th day of July, 1955.

SPENCER E. VAN DYKE and
JACK E. HILDRETH,
/s/ By SPENCER E. VAN DYKE,
Attorneys for Appellant
LAUGHLIN E. WATERS,
United States Attorney
/s/ By MAX F. DEUTZ,
Asst. U. S. Attorney, Chief of Civil Division,
Attorneys for Appellee

[Endorsed]: Filed July 11, 1955. Paul P. O'Brien, Clerk.